



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Philippa RADCLIFFE et al.

Title:

TRANSGENIC ORGANISM

Appl. No.:

10/082,122

Filing

02/26/2002

Date:

TECH CENTER 1600/2900

RECEIVED

NOV 2 7 2002

Examiner:

Unassigned

Art Unit:

1632

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT **UNDER 37 CFR §1.56**

Commissioner for Patents **Box PATENT APPLICATION** Washington, D.C. 20231

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a prima facie art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date NOV & 3, 200

FOLEY & LARDNER

Customer Number: 22428

22428

PATENT TRADEMARK OFFICE

Telephone: Facsimile:

(202) 672-5538 (202) 672-5399 Ву

Michele M. Simkin Attorney for Applicant Registration No. 34,717

July M Minlin

Approved for use through 10/31/2002. OMB 0651-0031,

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

number.

Sheet

Substitute f	or form 1449B/	PTO	*	Complete if Known	LIPE"
INFORMAT	ION DISCLO	SURE	Application Number Application	10/082,122	70
STATEMEN	IT BY APPLI	CANT	Filing Date	02/26/2002	- Mone
Date Submitted: November 25, 2002	First Named Inventor	Philippa RADCLIFFE	NOV 2 5 2002		
Date Submitte	a: November	23, 2002	Group Art Unit	1632	
(use as many	sheets as ne	cessary)	Examiner Name	Unassigned	E. S.
1	of	5	Attorney Docket Number	078883-0145	TRADE N

Attorney Docket Number

					F(DREIGN PATENT DOCUMENTS			
Examiner Initials*	Cite No.1	Fo Office ³	reign Patent D Number ⁴	ocument Kind C (if kno	ode ⁵	Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T 6
	A1	wo	91/10741	- /	A1	CELL GENESYS, INC.	07-25-1991		
	A2	WO	92/17505	/	Å1	BOARD OF REGENTS OF THE UNIVERSITY OF WASHINGTON	10-15-1992		
,	A3	wo	92/21766		A1	BOEHRINGER MANNHEIM GMBH et al.	12-10-1992		
	A4	wo ⁻	95/21927	/	A2	ISIS INNOVATION LIMITED.	08-17-1995 R	ECEIVED	
	A5	wo	98/05635	. [A1	CHIROSCIENCE LIMITED	02-12-1998	NOV 2 7 2002	
	A6	wo	98/07859		A2	GENETICS INSTITUTE, INC.	02-26-1998 TF C	CENTER 1600/290	0
	A7	wo	98/09985	. <i>į</i>	A2	YEDA RESEARCH AND DEVELOPMENT CO., LTD.	03-12-1998		
	A8	wo	98/15294		A1	THE UNIVERSITY OF SHEFFIELD	04-16-1998	_	
	A9	wo	98/17815	. /	A1	OXFORD BIOMEDICA LIMITED	04-30-1998		
	A10	wo	99/15683		A1	OXFORD BIOMEDICA LIMITED	04-01-1999		
	A11 -	wo	99/32646	. ,	A1	OXFORD BIOMEDICA LIMITED	07-01-1999	·	
	A12	wo	99/51755		A2	THE SALK INSTITUTE FOR BIOLOGICAL STUDIES	10-14-1999		
	A13	wo	01/79518		A2	OXFORD BIOMEDICA LIMITED	10-02-2001		

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁻⁶
	A14	BOWTELL et al., "Comparison of Expression in Hemopoietic Cells by Retroviral Vectors Carrying Two Genes," <u>Journal of Virology</u> , 62(7):2464-2473, American Society for Microbiology, July 1988	

Examiner Signature	 Date Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.

¹ Unique citation designation number. 2See attached Kinds of U.S. Patent Documents. 3Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.
Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.
Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

umber					<u> </u>	
	Substitute f	or form 1449B	/PTO		Complete if Known	CIRE
	INFORMAT	ON DISCLO	SURE	Application Number	10/082,122	10 AN
	STATEMEN	IT BY APPLI	ICANT	Filing Date	02/26/2002	MOV -0 E 2002 W
	Date Submitted	d. Navambar	25 2002	First Named Inventor	Philippa RADCLIFFE	NOV 2 5 2002 😤
	Date Submitted	ı: November	25, 2002	Group Art Unit	1632	18/
	(use as many	sheets as ne	ecessary)	Examiner Name	Unassigned	The same
Sheet	. 2	of	5	Attorney Docket Number	078883-0145	TRAUE TRAUE

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.
	A15	BRUCHSCHACHER & PANGANIBAN, "Human Immunodeficiency Virus Vectors for Inducible Expression of Foreign Genes," <u>Journal of Virology</u> , 66(5):2731-2739, American Society of Microbiology, May 1992
•	A16	BRUICK & McKNIGHT, "A Conserved Family of Prolyl-4-Hydroxylases That Modify HIF," <u>Science</u> , 294:1337-1340, November 9, 2001
	A17	CHAN et al., "Transgenic cattle produced by reverse-transcribed gene transfer in oocytes," Proc. Natl. Acad. Sci., 95:14028-14033, The National Academy of Sciences, November 1998
	A18	CHAN et al., "Transgenic Monkeys Produced by Retroviral Gene Transfer into Mature Oocytes," <u>Science</u> , 291:309-312, January 12, 2001
	A19	CLABOUGH et al., "Immune-Mediated Thrombocytopenia in Horses Infected with Equine Infectious Anemia Virus," <u>Journal of Virology</u> , 65(11):6242-6251, American Society for Microbiology, November 1991
	A20	COFFIN et al., "Retroviruses," pp. 683, 758-763, JM Coffin et al., eds., Cold Spring Harbour Laboratory Press, 1997
	A21	CORRELL et al., "Retroviral Vector Design for Long-Term Expression in Murine Hematopoietic Cells in Vivo," <u>Blood</u> , 84(6):1812-1822, The American Society of Hematology, September 15, 1994
	A22	CULLEN, "Regulation of HIV gene expression," AIDS, 9 (suppl A):S19-S32, Current Science Ltd., 1995
	A23	DERSE & NEWBOLD, "Mutagenesis of EIAV TAT Reveals Structural Features Essential for Transcriptional Activation and TAR Element Recognition," <u>Virology</u> , 194:530-536, Academic Press, Inc., 1993
	A24	DOUGHERTY & TEMIN, "A promoterless retroviral vector indicated that there are sequences in U3 required for 3' RNA processing," Proc. Natl. Acad. Sci., 84:1197-1201, USA, March 1987
,	A25	EMERMAN & TEMIN, "Genes with Promoters in Retrovirus Vectors Can Be Independently Suppressed by an Epigenetic Mechanism," Cell, 39:459-469, MIT, December 1984 (Part 2)
	A26	EPSTEIN et al., "C. elegans EGL-9 and Mammalian Homologs Define a Family of Liex och secural Regulate HIF by Prolyl Hydroxylation," Cell, 107:43-54, Cell Press, October 5, 2001
	A27	GHATTAS et al., "The Encephalomyocarditis Virus Internal Ribosome Entry Ste Allows Efficient Coexpression of Two Genes from a Recombinant Provirus in Cultured Cells and in Empryos (Machillar and Cellular Biology, 11(12):5848-5859, American Society for Microbiology, Pecephalogy (1994)

Examiner	
Signature	

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

	Substitute f	or form 1449B	/PTO		Complete if Known	PE
•	INFORMAT	ION DISCLO	SURE	Application Number	10/082,122	10
	STATEMEN	IT BY APPLI	CANT	Filing Date	02/26/2002	
r	Tata Cubmitta	d. Navamahan	25 2002	First Named Inventor	Philippa RADCLIFFE	MON 5 2 STOR
L	Date Submitted	i: November	25, 2002	Group Art Unit	1632	
	(use as many	sheets as ne	cessary)	Examiner Name	Unassigned	19 18
Sheet	3	of	5	Attorney Docket Number	078883-0145	ENT & TRADE

-		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.
	A28	GOODCHILD & KOHLI, "Ribozymes That Cleave an RNA Sequence from Human Immunodeficiency Virus: The Effect of Flanking Sequence on Rate," <u>Archives of Biochemistry and Biophysics</u> , 284(2):386-391, Academic Press, Inc., February 1, 1991
+	A29	HAASS & KAHLE, "Parkin and Its Substrates," Science, 293:224-225, July 13, 2001
	A30	HANTZOPOULOS et al., "Improved gene expression upon transfer of the adenosine deaminase minigene outside the transcriptional unit of a retroviral vector," <u>Proc. Natl. Acad. Sci.</u> , 86:3519-3523, May 1989, USA
	A31	HATZOGLOU et al., "Hormonal Control of Interacting Promoters Introduced into Cells by Retroviruses," The Journal of Biological Chemistry, 266(13):8416-8425, The American Society for Biochemistry and Molecular Biology, Inc., May 5, 1991, USA
	A32	HATZOGLOU et al., "Hormonal Regulation of Chimeric Genes Containing the Phosphoenolpyruvate Carboxykinase Promoter Regulatory Region in Hepatoma Cells Infected by Murine Retroviruses*," The Journal of Biological Chemistry, 263(33):17798-17808, The American Society for Biochemistry and Molecular Biology, Inc., November 25, 1988, USA
	A33	HAWLEY et al., "Handicapped retroviral vectors efficiently transduce foreign genes into hematopoietic stem cells," Proc. Natl. Acad. Sci., 84:2406-2410, USA, April 1987
	A34	HERMAN & COFFIN, "Efficient Packaging of Readthrough RNA in ALV: Implications for Oncogene Transduction," Science, 236:845-848, May 15, 1987
	A35	JOLLY et al., "Elements in the long terminal repeat of murine retroviruses enhance stable transformation by thymidine kinase gene," Nucleic Acids Research, 11(6):1855-1872, IRL Press Limited, Oxford, England, 1983
	A36	KITADA et al., "Mutations in the <i>parkin</i> gene cause autosomal recessive juvenile parkinsonism," <u>Nature</u> , 392:605-608, April 9, 1998
	A37	KRÜGER et al., "Ala30Pro mutation in the gene encoding α-synuclein in Parkinson's disease," Nature Genetics, 18:106-108, February 1998
	A38	LEWIS & EMERMAN, "Passage through Mitosis Is Required for Oncoretroviruses but Not for the Human Immunodeficiency Virus," <u>Journal of Virology</u> , 68(1):510-516, American Society for Microbiology, Jan 1994
	A39	LEWIS et al., "Human immunodeficiency virus infection of cells arrested in the cell cycle," The EMBO Journal, 11(8):3053-3058, Oxford University Press, 1992 NOV 2 7 2002

TECH CENTER 1600/2900

$\overline{}$				
Examiner	·	Date	· ·	
Signature _.		Considered	, ,	

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

nu<u>mber.</u>

	Substitute fo	r form 1449B	/PTO		Complete if Known	NPE"
	INFORMATION	ON DISCLO	SURE	Application Number	10/082,122	10 3
	STATEMENT	T BY APPLI	CANT	Filing Date	02/26/2002	-
	Date Submitted:	Nevember	25 2002	First Named Inventor	Philippa RADCLIFFE	NOV 2 5 2002
L	Jale Submitted	November	25, 2002	Group Art Unit	1632	i i
	(use as many s	heets as ne	cessary)	Examiner Name	Unassigned	3 ot
Sheet	4	of	5	Attorney Docket Number	078883-0145	TRADE MA

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.
	A40	LI et al., "Comparison of the Expression of a Mutant Dihydrofolate Reductase under Control of Different Internal Promoters in Retroviral Vectors," <u>Human Gene Therapy</u> , 3:381-390, Mary Ann Liebert, Inc., Publishers (1992)
	A41	MARTARANO et al., "Equine infectious Anemia Virus <i>trans</i> -Regulatory Protein Rev Controls Viral mRNA Stability, Accumulation, and Alternative Splicing," <u>Journal of Virology</u> , 68(5):3102-3111, American Society for Microbiology, May 1994
-	A42	MAURY et al., "Cellular and Viral Specificity of Equine Infectious Anemia Virus Tat Transactivation," <u>Virology</u> , 200:632-642, Academic Press, Inc., 1994
	A43	McLACHLIN et al., "Factors Affecting Retroviral Vector Function and Structural Integrity," <u>Virology</u> , 195:1-5, Academic Press, Inc. (1993)
	A44	NAGANO et al., "Transgenic mice produced by retroviral transduction of male germ-line stem cells," PNAS, 98(23):13090-13095, November 6, 2001
	A45	NALDINI et al., "In Vivo Gene Delivery and Stable Transduction of Nondividing Cells by a Lentiviral Vector Science 272:263-267, April 12, 1996
-	A46	OVERELL et al., "Stably Transmitted Triple-Promoter Retroviral Vectors and Their Use in Transformation of Primary Mammalian Cells," Molecular and Cellular Biology, 8(4):1803-1808, American Society for Microbiology, April 1988
	A47	POLYMEROPOULOS et al., "Mutation in the α-Synuclein Gene Identified in Families with Parkinson's Disease," <u>Science</u> , 276:2045-2047, June 27, 1997
	A48	ROULEUX et al., "A Negative Regulatory Element of the Macrophage-Specific Human Mannose Receptor Gene Represses Its Expression in Nonmyeloid Cells," <u>Experimental Cell Research</u> , 214:113-119, Academic Press, Inc., 1994
	A49	SCHARFMANN et al., "Long-term <i>in vivo</i> expression of retrovirus-mediated gene transfer in mouse fibroblast implants," Proc. Natl. Acad. Sci. , 88:4626-4630, USA, June 1991
	A50	SHIMURA et al., "Ubiquitination of a New Form of α-Synuclein by Parkin from Human Brain: Implications for Parkinson's Disease," <u>Science</u> , 293:263-269, July 13, 2001
	A51	VILE & RUSSEL, "Retroviruses as vectors," <u>British Medical Bulletin</u> , 51(1):12-30, The British Council (1995) NOV 2 7 2002

. U_. _R 1600/2900

Examiner		Date	
Signature	·	Considered	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

078883-0145

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

number.

Sheet

Complete if Known Substitute for form 1449B/PTO **Application Number** 10/082,122 INFORMATION DISCLOSURE STATEMENT BY APPLICANT Filing Date 02/26/2002 NOV 2 5 2002 Philippa RADCLIFFE **First Named Inventor** Date Submitted: November 25, 2002 Group Art Unit 1632 Examiner Name (use as many sheets as necessary) Unassigned TE TRADE

Attorney Docket Number

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.		
	A52	VILE et al., "A comparison of the properties of different retroviral vectors containing the murine tyrosinase promoter to achieve transcriptionally targeted expression of the HSVtk or IL-2 genes," Gene Therapy, 1:307-316, Macmillan Press, 1994		
v	A53	VILOTTE et al., "Modification and Repression of Genes Expressed in the Mammary Gland Using Gene Targeting and Other Technologies," <u>Journal of Mammary Gland Biology and Neoplasia</u> , 3(3):351-362, Plenum Publishing Corporation, 1998		
	A54	XU et al., "Factors Affecting Long-Term Stability of Moloney Murine Leukemia Virus-Based Vectors," Virology, 171:331-341, Academic Press, 1989		
, ,	A55	YEE et al., "A general method for the generation of high-titer, pantropic retroviral vectors: Highly efficient infection of primary hepatocytes," Proc. Natl. Acad. Sci., 91:9564-9568, USA, September 1994		
·	A56	YEE et al., "Gene expression from transcriptionally disabled retroviral vectors," Proc. Natl. Acad. Sci., 84:5197-5201, USA, August 1987		
	A57	YU et al., "Self-inactivitating retroviral vectors designed for transfer of whole genes into mammalian cells," Proc. Natl. Acad. Sci., 83:3194-3198, USA, May 1986		
	*			
		RECEIVED		
•		NOV 2 7 2002		
		TECH CENTER 1600/2900		

Examiner		Date	
Signature	•	Considered	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. 2See attached Kinds of U.S. Patent Documents. 3Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Skind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.